

## **REMARKS**

### **Interview**

On April 3, 2008, a telephonic interview was conducted between Applicants' representative and the Examiner, wherein the rejections under §101 and §112 were discussed. During the interview, the Examiner conceded that the specification provides enablement for the diagnosis and/or treatment of tumors but not for the other embodiments, such as, for example, preventing, reducing, following-up and/or after-caring, as presently claimed. The rejection under §101 rests on the contention that the recognition molecules are non-statutory since the amino acid sequences "can exist in nature."

Minor informalities with respect to claims 88, 96, 115 and 116 were discussed. See, *supra*.

### **Claims**

Claims 79–83 and 85–117 are currently under examination with claims 1–78 and 84 cancelled without prejudice or disclaimer. Claims 117–121 are added by this paper.

Applicants gratefully acknowledge that the subject matter of the claims is free of prior art.

### **Specification/Sequence Disclosure**

The specification has been amended to incorporate the sequence identifier number(s) of the various biological sequences contained therein. A copy of the revised sequence disclosure, in print and in electronic form, is also enclosed. No new matter is raised. Entry thereof is earnestly solicited.

### **Claim Amendments**

The claims have been amended to explicitly recite sequence identifier number(s) of the biological sequences.

Claims 88 and 96 have been recast as independent claims. The amendment of claim 98 is supported by the disclosure in Table 2 and the sequences recited therein.

New claims 117–121 are supported by, at least, the disclosure contained in the Examples and the information on the molecules of the present invention as explicitly recited in the attached sequence disclosure (i.e., synthetic).

It is respectfully submitted that the amendments presented herein do not raise new matter.

### **Priority**

A *copy* of a certified copy the German patent application with the Serial No. DE 10303664.4,

filed January 23, 2003 is enclosed herewith.

### **Claim objections**

The Examiner is thanked for her careful review of the claims. The forgoing amendments render the objection of claims 115 and 116 moot. Support for the sequence identifier numbers recited therein can be found in the revised sequence disclosure.

With respect to claims 88 and 96, Applicants submit that the forgoing amendments render the objection thereof moot. Furthermore, in view of the revised sequence disclosure, complete structural information on the genus of polypeptides (for example, SEQ ID NO: 1) and canonical structure variants thereof (for example, SEQ ID NO: 17–20), which comprise the recognition molecules of the present invention, is available to one of ordinary skill in the art. See, for example, pages 56–69 of the sequence listing.

### **Rejection under 35 U.S.C. §101**

The Office Action recommends that the claim term “recognition molecules” be amended to recite “antibodies.” Applicants thank the Examiner for her suggestions, but respectfully disagree. The claims convey to the skilled worker that the recognition molecules are polypeptides having the sequence set forth in the claims, wherein the structural (i.e., amino acid sequences) and the functional (i.e., capability to bind *specifically* to MUC-1 tumor epitope) aspects thereof are well-described in the originally-filed specification. Furthermore, in view of the reference publications enclosed herewith, it is submitted that the recognition molecules claimed herein are directed to statutory subject matter and not limited to antibody molecules, *per se*. For example, Skerra (*Journal of Molecular Recognition*, 2000), which was available before the earliest priority date of the present application, teaches methods for engineering novel protein scaffolds for molecular recognition. A subsequent publication by the same author (Skerra et al., *Current Opinion in Biotechnology*, 2007) teaches alternative non-antibody scaffolds for molecular recognition, including use thereof in therapeutics and proteomic research.

It is respectfully submitted that the discrete amino acid sequences or canonical structure variants thereof, as recited in the claims are clearly distinguished from naturally-existing molecules. The Examiner is further invited to review the disclosure contained in Applicants’ examples, wherein recognition molecules of the instant invention are obtained using recombinant techniques as opposed to extraction/purification from a natural source. Withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. §112, ¶1**

The rejection of claims 79–83, 85, 86 and 87–116 under 35 U.S.C. §112, first paragraph as allegedly lacking enablement is respectfully traversed.

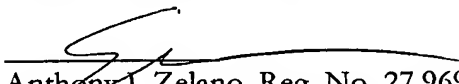
In the paragraphs spanning page 4 and 5, the Office Action alleges that the claims are non-enabling “for the prevention, diagnosis, reducing, follow up or after care of tumor diseases.” Applicants respectfully disagree with this contention. In essence, the Examiner is alleging lack of proof of use in prevention and treatment aspects. It is respectfully submitted that in view of Dr. Danielczyk’s declaration under §1.132 and the experimental evidence contained therein, this issue of is moot. For example, the studies outline the various uses of the recognition molecules of the present invention towards diagnostic, therapeutic, and/or preventive applications. Both *in vitro* and *in vivo* models were utilized.

Withdrawal of the rejection is respectfully requested.

In view of the above remarks, it is submitted that this application is in condition for allowance. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

  
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Attorney Docket No.: DORRIE-0020

Date: October 3, 2008  
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Encl:

(a) Copy of a certified copy of the priority document